

**Summary of the
Accreditation Process Committee Meeting
February 4, 1997**

The National Environmental Laboratory Accreditation Conference (NELAC) Quality Systems Committee met from 9:00 a.m. Eastern Standard Time (EST) on February 4, 1997. The meeting was led by Margaret M. Prevost. A list of action items is given in Attachment A. A list of Committee members/invited guests is given in Attachment B. A copy of the agenda is given in Attachment C.

INTRODUCTION

The purpose of the meeting was to continue to review revisions to Chapter 4, Accreditation Process Committee . The following items were discussed:

- Item No.1 -- Introduction/Progress Update
- Item No.2 -- Personnel Qualifications (Section 4.1.1)
- Item No. 3 -- On-site Assessment (Section 4.1.2)
- Item No. 4 -- Proficiency Testing (Section 4.1.3)
- Item No. 5 -- Interim Accreditation/Revocation (Sections 4.5.1-4.5.2)
- Item No. 6 -- Enforcement of Due Process (Section 4.7)
- Item No. 7 -- Other Issues

ITEM NO. 1 -- INTRODUCTION/PROGRESS UPDATE

Report of this committee comprises an overview of the all areas of the NELAC standards document. Note that this committee's report summarizes, but does not interpret, the standards prepared on these topics. The final report (Chapter 4) will reflect the final language used in the other chapters. Each section in this chapter will cross-refer to the chapter that it summarizes.

Items included on today's agenda comprise sections that have not yet been adopted.

It was noted that Illinois submitted a considerable number of comments focused on Chapter 4.

Due Process (Enforcement, Section 4.7) is not a topic covered by other chapters, and will be an important topic for today's session.

ITEM NO.2 -- PERSONNEL QUALIFICATIONS (SECTION 4.1.1)

Illinois Blue Paper, Attachment 1, notes that Section 4.1.1, paragraph 1, sentence 5 is not needed and is a potential conflict with ISO 58 section 4.1.1. Also, Section 4.1.1, paragraph 1, sentence 7 is an unnecessary administrative function and if a data quality problem is created due to the absence of the responsible party of record this will be manifested by a nonconformance with the requirements of Chapter 5.

1. Full-time dedicated director (responsible person of record)

Comments from Illinois: Qualifications should be streamlined. Part of the section could restrict multiple laboratories from using the same director.

2. Credential requirements

Could consider distinguishing credentialing requirements by specific types of tests. Chapter 4 currently is intended to leave leeway in the definition of requirements to the State authorities and/or laboratories. Concept was to provide an overview of all types of laboratories (e.g., including small water system labs). The representative from Ohio was asked to provide specific comments in this realm.

Comments from South Carolina representative: Agrees that NELAC will need to establish standards for credentialing. Also agrees with the grandfathering language (see below).

In Louisiana, there are separate certifying authorities (e.g., the Health Department has purview over drinking water labs) for various types of labs.

Note that laws in many states cannot/will not be changed based on NELAC standards for all types of labs.

Suggest looking at language about whether multiple persons could be responsible persons of record.

4.1.1 language about absences of director would appear to require considerable paperwork to the authority. Note that this only applies if there is only one responsible person of record. If others (e.g., assistant directors) have been designated, this would not be a problem.

Action item: Clarify section 4.1.1 language regarding absence of responsible person of record.

Health physicists are involved with personnel exposure to radiation. The field appears to be similar to the field of radiochemistry.

4.1.1.e Language regarding requirements for degrees could be more specific as to the type of science background is optimal. Paul Martin will send information on the requirements for the TEM (transmission electron microscopy) labs with which he is involved.

Action item: Clarify degree requirements for 4.1.1.e (i) - asbestos testing.

3. Grandfathering -- legal necessity

Suggest adding language that 'Requirements are as defined by the State certification process. 4.1.1.g and 4.1.1.i seem to allow for some leeway in grandfathering in people who are already performing particular responsibilities.

ITEM NO. 3 -- ON-SITE ASSESSMENT (SECTION 4.1.2)

1. Maintain consistency with Chapter 3

Once the On-site Assessment Committee completes their report (Chapter 3), the Accreditation Process will produce a summary of the report for section 4.1.2. Therefore, it would be most appropriate if specific feedback on this topic should be submitted to the On-site Assessment Committee.

2. Revisions to 4.1.2 (12/6/96 version)
3. CBI statements in Chapter 3 consistent with those in 4.1.2.c.

The last sentence of paragraph 2 should be revised.

Section 4.1.2.e - Marginal performance will be defined by the appropriate committee.

Section 4.1.2.f - Change language to 'appropriate for the laboratory size', in place of excessive.

Section 4.1.2.c - Revise CBI statements to be consistent with Chapter 3, when finalized.

Section 4.1.2.b - Suggest striking 'any or' from this item. No, refer to Chapter 3 for any revisions. See 3.4.2, last sentence

4. Definition of what categories/methods must be assessed (make consistent with Chapter 3)

Some discussion focused on the appropriateness of unannounced visits.

5. Combine 4.1.2 and 4.3.2
6. Delete 4.1.2.h and corresponding statement in Chapter 3.
7. Delete second and third sentences of 4.1.2.d. Probably only need first sentence.

ITEM NO. 4 -- PROFICIENCY TESTING (SECTION 4.1.3)

1. Clarify section 4.1.3.c based on revisions of the final report from the Proficiency Testing Committee (consistent with Chapter 2).

ITEM NO. 5 -- INTERIM ACCREDITATION/REVOCATION (SECTIONS 4.5.1-4.5.2)

Note this section only appears in this chapter.

Interim accreditation may be a short-term need. The goal would be that interim accreditation be unnecessary as the NELAC accreditation program develops.

1. Delete second paragraph in section 4.5.1; reconcile with Chapter 6.
2. Reference in 4.5.2 should be changed from '4.4.0' to '4.4'.
3. Change language to 'interim authorization.'
4. Some discussion focused on whether the language in the first sentence of section 4.5.1 should include 'shall' versus 'may'. It was determined that this would be inappropriate.
5. Section 4.5.1 - Change 'shall' to 'should' in fourth sentence. Change 'may' to 'shall' in fifth sentence.

Overall, incorporation of the NELAC standards into State authorities will be a gradual process. The process for NELAC accreditation is described in Chapter 6.

ITEM NO. 6 -- ENFORCEMENT OF DUE PROCESS (SECTION 4.7)

Section 4.7 was adopted previously. Clarifications were to be suggested at this meeting.

1. What failures cause decertifications?

PT will take care of.

2. Appeals process

Will only cover administrative versus judiciary aspects.

See 4.4.1 and 4.4.2 last sentence.

Action items: Clarify language in section 4.4.2 and 4.4.3 regarding revocation and suspension, and remove reference to 'downgrading' in section 4.4.3 and coordinate with On-site Assessment Committee.

3. Due process laws -- differences among states.

Issues of reciprocity were discussed. Due process may be affected by reciprocity in some states. Committee members pointed out similarities among the states in actions taken towards laboratories, but due process differences occur in cases of partial decertification. As long as the differing state's data are submitted to the national database, other states can reach their own decisions regarding allowing a lab component decertified in one state to continue (or not) to work

in the other state. (e.g., A lab component could be decertified in New York and still be allowed to appeal and continue in Illinois.)

Whatever the NELAC standards regarding decertification, state authority will still have ultimate authority of due process issues.

4. Specific changes noted. See Action Items.

ITEM NO. 7 -- OTHER ISSUES

1. Personnel Standards -- 'grandfather clause'
 - A. Standardized date
 - B. No 'sunset clause'
2. Section 4.6 - Check consistency of language on wording on certificates with Chapters 1 and 6.
3. Accrediting authorities other than states

CONCLUSION

The Chairperson, Margaret Prevost, concluded the committee meeting by encouraging participants to submit any further written comments to the Committee chair.

In summary:

- All revisions suggested at this meeting will be incorporated into the chapter.
- Committee will review and incorporate any further written comments submitted.
- Committee will review document and review for consistency and appropriate use of language.

NEXT CONFERENCE

The next meeting is scheduled for July 1997.

ACTION ITEMS
Accreditation Process Committee Meeting
February 4, 1997

Item No.	Action	Date Completed
1	Clarify section 4.1.1 language regarding absence of responsible person of record.	
2	Clarify degree requirements for 4.1.1.e (i) - asbestos testing.	
3	Incorporate revisions to 12/6/96 version of section 4.12 (On-site Assessment).	
4	Combine 4.1.2 and 4.3.2.	
5	Overall, streamline Chapter 4.	
6	Clarify section 4.1.3.c based on revisions of the final report from the Proficiency Testing Committee (consistent with Chapter ?).	
7	Delete second paragraph in section 4.5.1; reconcile with Chapter 6.	
8	Section 4.5.1 - Change 'shall' to 'should' in fourth sentence. Change 'may' to 'shall' in fifth sentence.	

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Item No.	Action	Date Completed
9	Clarify language in section 4.4.2 and 4.4.3 regarding revocation and suspension, and remove reference to 'downgrading' in section 4.4.3 and coordinate with On-site Assessment Committee.	
10	Section 4.7 - References to NELAC should be changed to NELAP. Eliminate the second sections (b), (c), and (d). Delete sentence following first section (d). Leave second (a) as a stand-alone paragraph rewritten to clarify that NELAP would never take any enforcement action.	
11	Remove reference to 'poor performance from Section 4.3.1 and elsewhere.	
12	Change references from 'EPA' to 'US EPA'.	
13	Section 4.4 should be 'Denial, Revocation, Suspension, and Voluntary Withdrawal'	
14	Section 4.4.1 - Change 'renewal of accreditation' to 'resubmission'	
15	Change Section 4.4.1.d.	

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Item No.	Action	Date Completed
16	Section 4.1.4 - Delete 'revoked or'.	
17	Section 4.4.2 - Replace 'state authority' with 'accrediting authority'.	
18	Reword Section 4.4.2(b).	
19	Remove 'or denied' from last sentence of Section 4.4.2.	
20	Ensure consistent use of 'accrediting authorities', in place of States	
21	Section 4.4.3 - Move reference to '6 months' from the third to the first sentence.	
22	Section 4.4.3 - Delete fourth sentence.	
23	Section 4.6 - Check what information goes on certificates (check with other committees).	
24	Insert a summary section on Quality Systems.	

LIST OF COMMITTEE/CONFERENCE PARTICIPANTS
Accreditation Process Committee Meeting
February 4, 1997

Name	Affiliation	Phone/Fax/E-mail
Margaret M. Prevost	New York State Department of Health	T: 518/485-5570 F: 518/485-5568 E: mmpo3@health.state.ny
Peter Spath	Eastman Kodak Company	T: 716/588-0801 F: 716/722-4406 E: pspath@kodak.com
Zonetta E. English	Louisville Jefferson Co. Metro. Sewer Dist.	T: 502/540-6706 F: 502/540-6779 E: zenglish@aol.com
Stevie Wilding	USEPA, Region III	T: 410/573-2733 F: 410/573-6888 E: wilding.stevie@epamail.epa.gov
Janet S. Cruse	Illinois EPA, Division of Laboratories	T: 217/782-6455 F: 217/524-0944 E: epa.6111@epa.state.il.us

**AGENDA
Accreditation Process Committee Meeting
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Introduction; Progress Update	9:00-9:20 a.m.
Personnel Qualifications	9:20-10:15 a.m.
On-site Assessment	10:30-11:00 a.m.
Proficiency Testing	11:00-11:30 a.m..
Interim Accreditation/Revocation	11:30-12:00 p.m.
Enforcement on Due Process	1:00-2:00 p.m.
Other Issues	2:00-3:00 p.m.